REMARKS

Status of the application

Claims 1-39, 40-42 and 44-45 were pending in the application, with claims 1-39 being withdrawn by the Examiner as directed to non-elected invention, and claims 40-42 and 44-45 stand rejected. With entry of the instant response, claims 1-39 have been canceled, Claim 40 has been amended, and new claims 48-58 are added.

Specifically, Claim 40 has been amended to delete a previously inserted element, i.e., "the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria." New claims 48-53 respectively mirror original claims 40-45. Compared to the newly amended independent claim 40, new independent claim 48 recites that "the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria when exposed to light" but does not recite "the source of singlet oxygen is not covalently attached to the antibody." Similarly, new claims 54-58 parallel to original claims 40-42 and 44-45, respectively. Unlike independent claims 40 and 48, independent claim 54 recites both "the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria when exposed to light" and "the source of singlet oxygen is not covalently attached to the antibody."

As pointed out in Applicants' earlier submissions, the recitation of "the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria" is provided in the specification, e.g., at page 82, line 29 to page 83, line 1. The new claims introduced herein also contain an additional claim element "when exposed to light." Support for use of sources of singlet oxygen that do not, by themselves, kill bacteria when exposed to light can be found throughout the specification and claims as originally filed, e.g., in the Examples (see, e.g.,

page 83, lines 6-10).

As further explained below, the present claim amendment and new claims introduced herein do not contain no new subject matter. Entry of the instant listing of claims is therefore respectfully requested. The following remarks are provided to address the specific issues raised in the outstanding Office Action dated August 1, 2006.

Priority Claims

The Examiner asserted that the presently claimed invention is not entitled to a priority claim to Application Ser. No. 60/426,**242** filed on November 14,2002. Applicants note that Application Ser. No. 60/426,**242** was apparently mistaken for Application Ser. No. 60/426,**245** (also filed on November 14, 2002) by the Examiner. It is also noted that the Examiner's previous criticism on Applicants' priority claim was not directed to application 60/426,**242**. Rather, it was directed to application 60/426,**245** and several other earlier filed applications, .

The Examiner is advised that application 60/426,**245** was listed as a related application in the subject specification. On the other hand, application 60/426,**242** is the provisional application from which the subject application directly derived and to which priority is claimed. A cursory review of Application Ser. No. 60/426,**242** (e.g., the claim section) would reveal that the presently claimed invention was disclosed therein.

Thus, even if the present claims do not enjoy the priority date of application 60/426,**245** and the other earlier filed applications, as alleged by the Examiner, they are nonetheless entitled to a priority date of November 14, 2002 through the priority claim to application 60/426,**242**. If the Examiner still

has any doubt, she is invited to review the disclosure of Application Ser. No. 60/426,**242** (not 60/426,**245**).

Specification

In the Office Action dated August 1, 2006, it was stated that the previously submitted substitute specification was not entered, allegedly because Applicants have not submitted a marked-up version of the specification with the appropriate markings to show all the changes made. As clarified in Applicants' response of November 1, 2006, Applicants have previously submitted both a marked-up copy and a clean copy of the noted substitute specification. These submissions were entered by the US Patent and Trademark Office on May 10, 2006, as evidenced by the documents that can be retrieved from Image File Wrapper of the Public Pair records of the subject application on the website of the U.S. Patent and Trademark Office.

Therefore, Applicants have complied with the requirements for submitting a substitute specification. Entry of the previously submitted Substitute Specification is accordingly requested.

Written description rejection under 35 U.S.C. §112, 1st paragraph

Claims 40-45 were rejected as allegedly failing to comply with the written description requirement. The Examiner alleges that there is no teaching in the specification of a source of singlet oxygen that is not covalently attached to the antibody. Applicants respectfully traverse this rejection for the reasons set forth below.

Applicants first note that the Examiner apparently has applied a verbatim and literal support standard in making the instant rejection. However, such is not the legal test for

written description requirement. Rather, the written description requirement "does not require in haec verba antecedence in the specification." *Staehelin v. Secher*, 24 USPQ2d 1111, 1117 (Fed. Cir. 1991; emphasis added). All that is required is that "the description convey with reasonable clarity to person of skill in the art that the inventor was in possession of whatever is now claimed." *Vas-Cath v. Mazurka*, 935 F.2d 1555, 19 USPQ2d 1111,1117 (Fed. Cir. 1991). If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996; emphasis added). Consistent with the case law, the MPEP also states that "[t]he subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." (MPEP § 2163.02; emphasis added).

Further, it should be emphasized that mere rephrasing of a passage does not constitute new matter. "A rewording of a passage where the same meaning remains intact is permissible." See *In re Anderson*, 471 F.2d 1237 (CCPA 1973) and MPEP 2163.07-I. Further, as stated in the MPEP, other than express disclosure, claim limitations can also be supported in the specification by implicit or inherent disclosure (See, e.g., MPEP. § 2163-I-B).

Turning to the instant case, Applicants submit that support clearly exists for use of sources of singlet oxygen that are not covalently attached to the antibody throughout the application as filed. For example, Example III and FIG. 14A-D explicitly illustrate use of source of singlet oxygen that is not covalently attached to the antibody. The Examiner's attention is directed

to, e.g., description of "Bactericidal Assays" in the specification at page 77, line 27 to page 78, line 5. A portion of this description of the "Bactericidal Assays' is reproduced below for easy reference.

> -- In a typical experiment, a culture of E. coli (in log phase growth, OD_{600}=0.2-0.3) was repeatedly pelleted (3 x 3,500 rpm) and resuspended in PBS (pH 7.4). The PBS suspended cells were then added to glass vials and cooled to 4°C. **Hematoporphyrin IX (40 μM) and antibody (20 μM)** were added... (see page 77, line 28 to page 28, line 2)-- [emphasis added]

In this passage of the specification, the concentrations of antibody (20 μM) and hematoporphyrin (40 μM) are different and separately described. This clearly indicates that these two molecules are not conjugated together, certainly not covalently attached to each other. In addition, the specification at page 25, line 4 merely states that "in some embodiments" (i.e., not all) a sensitizer is conjugated to an antibody. This clearly implies that there are some other embodiments in which the source of singlet oxygen is not covalently attached to the antibody.

As clarified above, written description does not require verbatim and literal antecedence in the specification. Rather, claim limitations can be supported by implicit or inherent disclosure. Based on the above noted teachings of the subject specification, no one would doubt that the specification has provided more than the required implicit or inherent disclosure to support the recited claim element ("the source of singlet oxygen is not covalently attached to the antibody"). The law of written description does not ask anything more than such disclosure in order to satisfy the description and support requirement under 35 U.S.C. § 112. Therefore, Applicants

respectfully urge that the instant rejection be withdrawn. If the Examiner nonetheless chooses to maintain the instant rejection, Application respectfully request the Examiner to provide adequate legal basis for the literal support standard that is apparently demanded by the Examiner.

Novelty rejection under 35 U.S.C. §102

The previous pending claims were also rejected as allegedly anticipated by each of Devanathan et al. (Proc. Nat'l. Acad. Sci. USA 87:2980-2984, 1990), Berthiaume et al. (Biotechnol. 12:703-706, 1994), and the Scripps Press Release of November 14,2002. The Examiner alleged that each of these references anticipated the subject invention because they teach a method of usi ng an antibody and a source of singlet oxygen to inhibit bacterial growth. For the reasons stated below, Applicants respectfully traverse this rejection to the extent that it may be applied to the presently amended claims and the new claims introduced herein.

To constitute anticipation, a single prior art reference must disclose each and every element of the claimed invention. See, e.g., *Verdegaal Bros. v. Union Oil of California,* 814 F.2d 628,631,2 USPQ2d 1051,1053 (Fed. Cir. 1987); and *In re Arkley,* 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). As detailed below, none of the cited references satisfies such legal requirements for anticipating the present claims.

First, Devanathan et al. and Berthiaume et al. discuss the use of antibodies as targeting vehicles to deliver phototoxic agents (fluorescein isothiocyanate in Devanathan et al. and tin (IV) chlorin e_6 in Berthiaume et al.) to kill bacteria. As explained previously, the antibodies in both references are covalently conjugated to the phototoxic agents. In addition, as

acknowledged by the Examiner (Office Action dated August 1, 2006, at page 8), the phototoxic agents conjugated to the antibodies in these two references become toxic (i.e., bactericidal) only when exposed to light.

Devanathan et al. and Berthiaume et al. did not and could not anticipate the subject invention because, unlike the subject invention, they do not teach the use of antibodies to catalyze the production of ozone (from singlet oxygen) as the active bactericidal agent. In addition, the present claims are also novel over Devanathan et al. and Berthiaume et al. because one or more of the elements expressly recited in the present claims is not disclosed in the cited references. Specifically, Claim 40 and dependent claims specify the use of a source of singlet oxygen that is not covalently attached to the antibody. Therefore, these claims are also novel over Devanathan et al. and Berthiaume et al. which do not teach this element of the noted claims. Similarly, Claim 48 and dependent claims are novel because they recite a source of singlet oxygen which would not on its own inhibit the growth of the bacteria <u>when exposed to light</u>. Such a feature was not disclosed in Devanathan et al. or Berthiaume et al. For the same reasons, claims 53 and dependent claims are novel because they recite both "a source of singlet oxygen that is not covalently attached to the antibody" and "a source of singlet oxygen which would not on its own inhibit the growth of the bacteria when exposed to light." In contrast, none of these two features was disclosed in Devanathan et al. or Berthiaume et al.

Turning to the Scripps Press Release, this citation also could not anticipate the present claims. As clarified above, the presently claimed invention has a priority date of at least as early as November 14, 2002 through the priority claim to

Application Ser. No. 60/426,**242**, filed November 14, 2002. Therefore, the Scripps Press Release dated November 14, 2002 is not prior art against the present invention. As such, the rejection under 35 U.S.C. § 102(b) based on this reference cannot be maintained.

For all the reasons and clarifications presented herein, it is clear that the presently claimed invention is novel over the cited references. Accordingly, the instant rejection should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that the claims now pending in the subject patent application are in condition for allowance, and notification to that effect is earnestly requested. If needed, the Examiner is invited to telephone Applicant's attorney at (858) 784-2937 to facilitate prosecution of this application.

The Director is hereby authorized to charge our Deposit Account No. 19-0962 in the event that there are any additional charges associated with the present Petition or any Response in connection with this application.

Respectfully submitted,

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Date

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